Appendix B
Clean Version Upon Entry of the Preliminary Amendment

In the Specification:

On page 1, beginning at line 5, the substituted paragraph will read:

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of, and claims the benefit of priority from, application Ser. No. 09/128,401; filed on Aug. 3, 1998, now U.S. Pat. No. 6,080,721, which is a division of application Ser. No. 08/625,586; filed on Mar. 28, 1996, now U.S. Pat. No. 5,814,607, which is a continuation of application Ser. No. 08/232,849; filed on Apr. 25, 1994, now U.S. Pat. No. 5,607,915, which is a continuation of application Ser. No. 07/953,397; filed on Sep. 29, 1992, now abandoned, the full disclosures of which are incorporated herein by reference.

The substituted paragraph bridging paragraphs 10 and 11 will read:

For use in MDI's, the PTH fragments of the present invention will be dissolved or suspended in a suitable aerosol propellant, such as a chlorofluorocarbon (CFC) or a hydrofluorocarbon (HFC). Suitable CFC's include trichloromonofluoromethane (propellant 11), dichlorotetrafluoroethane (propellant 114), and dichlorodifluoromethane (propellant 12). Suitable HFC's include tetrafluoroethane (HFC-134a) and heptafluoropropane (HFC-227).

In the Claims:

The claims will read:

20. A pharmaceutical composition consisting essentially of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant, wherein the composition is housed within a device designed for delivering an aerosolized bolus through the mouth.

21. The pharmaceutical composition of claim 20, wherein the aerosol propellant comprises a chlorofluorocarbon or a hydrofluorocarbon.

24. The pharmaceutical composition of claim 20, wherein the aerosol propellant comprises a chlorofluorocarbon.

25. The pharmaceutical composition of claim 24, wherein the chlorofluorocarbon is selected from the group consisting of trichloromonofluoromethane, dichlorotetrafluoroethane, dichlorodifluoromethane, and combinations thereof.

26. The pharmaceutical composition of claim 20, wherein the aerosol propellant comprises a hydrofluorocarbon.

27. The pharmaceutical composition of claim 26, wherein the hydrofluorocarbon is selected from the group consisting of tetrafluoroethane, heptafluoropropane, and combinations thereof.

28. The pharmaceutical composition of claim 20, wherein the composition comprises a powder having a mean particle size in the range from 0.5 μm to 5 μm.

29. The pharmaceutical composition of claim 20, wherein the bulking agent is selected from the group consisting of sucrose, lactose, trehalose, human serum albumin, glycine, cellobiose, dextrans, maltotriose, pectin, sodium citrate, sodium ascorbate, mannitol, and combinations thereof.

30. The pharmaceutical composition of claim 20, wherein the biologically active N-terminal fragment of parathyroid hormone is PTH34.

31. The pharmaceutical composition of claim 20, wherein the biologically active N-terminal fragment of parathyroid hormone is PTH38.

32. A pharmaceutical composition comprising a biologically active N-terminal fragment of parathyroid hormone and a propellant, wherein the composition lacks a penetration enhancer

and further wherein the composition is housed within a device designed for delivering an aerosolized bolus through the mouth.

33. The pharmaceutical composition of claim 32, wherein the aerosol propellant comprises a chlorofluorocarbon or a hydrofluorocarbon.

34. The pharmaceutical composition of claim 32, wherein the aerosol propellant comprises a chlorofluorocarbon.

35. The pharmaceutical composition of claim 34, wherein the aerosol propellant is selected from the group consisting of trichloromonofluoromethane, dichlorotetrafluoroethane, dichlorodifluoromethane, and combinations thereof.

36. The pharmaceutical composition of claim 32, wherein the aerosol propellant is a hydrofluorocarbon.

37. The pharmaceutical composition of claim 36, wherein the aerosol propellant is selected from the group consisting of tetrafluoroethane, heptafluoropropane, and combinations thereof.

38. The pharmaceutical composition of claim 32, wherein the composition comprises a powder having a mean particle size in the range from 0.5 μm to 5 μm.

39. The pharmaceutical composition of claim 32, further comprising a bulking agent.

40. The pharmaceutical composition of claim 39, wherein the bulking agent is selected from the group consisting of sucrose, lactose, trehalose, human serum albumin, glycine, cellobiose, dextrans, maltotriose, pectin, sodium citrate, sodium ascorbate, mannitol, and combinations thereof.

41. The pharmaceutical composition of claim 32, wherein the composition further comprises an additive.

42. The pharmaceutical composition of claim 41, wherein the additive is selected from the group consisting of surfactants, lower alcohols, chemical stabilizers and combinations thereof.

43. The pharmaceutical composition of claim 42, wherein the additive is a surfactant.

44. The pharmaceutical composition of claim 43, wherein the surfactant is selected from the group consisting of oleic acid, sorbitan trioleate, long chain diglycerides, phospholipids, and combinations thereof.

45. The pharmaceutical composition of claim 43, wherein the composition comprises a powder comprised of particles and further wherein the particles are coated with the surfactant.

46. The pharmaceutical composition of claim 41, wherein the additive is a lower alcohol.

47. The pharmaceutical composition of claim 46, wherein the lower alcohol is ethanol.

48. The pharmaceutical composition of claim 41, wherein the additive is a chemical stabilizer.

49. The pharmaceutical composition of claim 48, wherein the chemical stabilizer is selected from the group consisting of buffers, salts, and combinations thereof.

50. The pharmaceutical composition of claim 49, wherein the chemical stabilizer is a buffer.

51. The pharmaceutical composition of claim 50, wherein the buffer is selected from the group consisting of phosphate buffers, citrate buffers, acetate buffers, tris-HCl buffers, and combinations thereof.

52. The pharmaceutical composition of claim 45, wherein the wherein the chemical stabilizer is a salt.

53. The pharmaceutical composition of claim 52, wherein the salt is selected from the group consisting of sodium chloride, sodium carbonate, calcium chloride, and combinations thereof.

54. The pharmaceutical composition of claim 32, wherein the biologically active N-terminal fragment of parathyroid hormone is PTH34.

55. The pharmaceutical composition of claim 32, wherein the biologically active N-terminal fragment of parathyroid hormone is PTH38.

56. A method for treating a mammalian host suffering from or at risk of osteoporosis comprising administering by inhalation through the mouth of the host an aerosolized bolus of a pharmaceutical composition consisting essentially of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone, a pharmaceutically acceptable bulking agent and an aerosol propellant.

57. The method of claim 56, wherein the mammalian host is human.

58. A method for treating a mammalian host suffering from or at risk of osteoporosis comprising administering by inhalation through the mouth of the host an aerosolized bolus of a pharmaceutical composition comprised of a therapeutically effective amount of a biologically active N-terminal fragment of parathyroid hormone and a propellant, wherein the composition lacks a penetration enhancer.

59. The method of claim 58, wherein the mammalian host is human.